October 04, 2019

DePuy(Ireland)
% Ashley Goncalo
Project Manager-Regulatory Affairs
DePuy Orthopaedies, Inc.
700 Orthopaedies Dr.
Warsaw, Indiana 46582

Re: K192448
Trade/Device Name: DELTA XTEND™ Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD
Dated: September 4, 2019
Received: September 6, 2019

Dear Ashley Goncalo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael C. Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192448

Device Name
DELTA XTEND Reverse Shoulder System

Indications for Use *(Describe)*

The DELTA XTEND Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with:
- severe arthropathy and/or;
- a previously failed joint replacement and/or:
- fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

DELTA XTEND hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the revision of a previously failed DELTA XTEND Reverse Shoulder.
The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation.
The modular humeral stem and humeral epiphysis components are HA coated and intended for cementless use. All other metallic components are intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

As required by 21 CFR 807.92 and 21 CFR 807.93

Submission Information		
Sponsor Name	DePuy (Ireland)	
Sponsor Address	Loughbeg, Ringaskiddy Co. Cork Ireland	
Sponsor Establishment Registration Number	9616671	
510(k) Contact	Ashley Goncalo DePuy Synthes Regulatory Project Manager	Phone: 508.977.3907 Email: agoncalo@its.jnj.com
Date prepared	September 4, 2019	
Device Information		
Trade or proprietary name	DELTA XTEND™ Reverse Shoulder System	
Common or usual name	Shoulder Prosthesis	
Classification name	Shoulder joint metal/polymer semi-constrained cemented prosthesis	
Class, regulation	Class II, 21 CFR 888.3660	
Product Code	PHX, HSD	
Classification panel	Orthopedics panel	
Legally marketed device(s) to which equivalence is claimed	DELTA XTEND Reverse Shoulder System (DePuy: K062250, K071379, K120174)	
Reason for 510(k) submission	Introduction of an additional manufacturing and sterilization site for the hydroxyapatite (HA) coated system components that are marketed as part of the DELTA XTEND Reverse Shoulder System. Additionally, there is an update to packaging configuration for these system components.	
Device description	The DELTA XTEND Reverse Shoulder System is currently cleared and marketed by DePuy Synthes and is comprised of multiple humeral and glenoid implant components. These are provided as separate, standalone devices and may be used in conjunction to form a total shoulder prothesis. This submission is pertinent to only those system components which are HA coated: • Humeral Implants: o Modular humeral stems o Modular epiphysis • Glenoid Implants: o Metaglenes	

Intended use of the device	The DELTA XTEND Reverse Shoulder prosthesis is intended for use in total or hemi-shoulder arthroplasty procedures in patients with non-functional rotator cuffs, with or without bone cement.
Indications for use	The DELTA XTEND Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with: • severe arthropathy and/or; • a previously failed joint replacement and/or: • fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. DELTA XTEND hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the revision of a previously failed DELTA XTEND Reverse Shoulder. The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. The modular humeral stem and humeral epiphysis components are HA coated and intended for cementless use. All other metallic components are intended for cemented use only.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**Subject Device: DePuy Synthes DELTA XTEND™ Reverse Shoulder System**	**Predicate Device: DePuy Synthes DELTA XTEND™ Reverse Shoulder System (**K062250, K071379, K120174)
Intended Use	Reverse shoulder arthroplasty	Reverse shoulder arthroplasty
Material		
Humeral Implants (Modular Humeral Stem, Modular Epiphysis)	Titanium alloy with HA coating	Titanium alloy with HA coating

Glenoid Implants (Metaglene)		
Design		
Humeral Implants (Modular Humeral Stem, Modular Epiphysis)	Modular, without cement, composed of an epiphysis and a humeral stem made out of titanium and coated with hydroxyapatite. The epiphysis is available in standard or long version and in two sizes in order to be able to adapt as well as possible to the human anatomy. The distal stem is available in several diameters to maximize the adaptability of humeral canal.	Modular, without cement, composed of an epiphysis and a humeral stem made out of titanium and coated with hydroxyapatite. The epiphysis is available in standard or long version and in two sizes in order to be able to adapt as well as possible to the human anatomy. The distal stem is available in several diameters to maximize the adaptability of humeral canal.
Glenoid Implant (Metaglene)	The Glenoid Implant is comprised of a glenosphere that is fixed on the metaglene by a conical joint and a central pin. The metaglene is coated with hydroxyapatite and is fixed inside the bone with 4 screws. **This submission pertains to the metaglene component of the Glenoid Implant only.**	The Glenoid Implant is comprised of a glenosphere that is fixed on the metaglene by a conical joint and a central pin. The metaglene is coated with hydroxyapatite and is fixed inside the bone with 4 screws
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
The following tests were performed on the DELTA XTEND Reverse Shoulder System to demonstrate substantial equivalence of safety and efficacy with the predicate devices: • Biological safety per ISO 10993-1 "*Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*". • Packaging validation per ISO 11607-1 and ISO 11607-2 utilizing ISTA 3A. • Sterilization validation per AAMI ANSI ISO 11137-1: 2006/(R)2010 and AAMI ANSI ISO 11137-2: 2013		

• Characterization testing of Hydroxyapatite Coating as recommended per FDA Guidance: *"510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implant"*
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
No clinical tests were conducted to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The HA coated Modular Humeral Stem, Modular Epiphysis, and Metaglene of the DELTA XTEND Reverse Shoulder System is substantially equivalent to the HA coated Modular Humeral Stem, Modular Epiphysis, and Metaglene of the predicate DePuy Synthes DELTA XTEND Reverse Shoulder System (K062250, K071379, K120174).